

In re Application of:
Griffin, et al.
Serial No.: 09/606,779
Filed: June 28, 2000
Page 3

PATENT
Attorney Docket No.: SCRIP1180-3

b) comparing the clotting time for the test reaction to the clotting time for a control reaction carried out under the same conditions as the test reaction, but with a control sample comprising a coagulation factor V or Va-containing specimen from an individual not having or not at risk of having a thrombotic disorder associated with APC-resistant factor V or Va, wherein:

i) detection of a decreased clotting time in the test reaction relative to the control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va;
and

ii) detection of a similar clotting time in the test reaction relative to the control reaction indicates that the subject does not have or is not at risk of developing a thrombotic disorder associated with APC-resistant factor V or Va.

3. The method of claim 2, wherein the specimen from the subject is previously frozen plasma.

4. The method of claim 2, wherein the thrombotic disorder is thrombophilia.

5. The method of claim 2, wherein the thrombotic disorder is due to a factor V mutation.

6. The method of claim 5, wherein the mutation results in a change from arginine to glutamine at position 506 of factor V.

7. The method of claim 2, wherein the procoagulant reagent comprises tissue factor.

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Page 4

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8. The method of claim 2, wherein the procoagulant reagent comprises a phospholipid.

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82 9. The method of claim 8, wherein the phospholipid is present at a concentration of about 5-100 uM in the test sample.

10. The method of claim 8, wherein the phospholipid is present at a concentration of about 10-50 uM in the test sample.

11. The method of claim 2, wherein the procoagulant reagent comprises an activator of the intrinsic coagulation pathway.

12. The method of claim 11, wherein the activator is a clotting factor selected from the group consisting of factor Xa, factor IXa, factor XIa and factor XIIa.

13. The method of claim 2, wherein the procoagulant is a reagent selected from the group consisting of kallikrein, Russell's viper venom, micronized silica particles, ellagic acid, sulfatides, kaolin, and tissue thromboplastin.

14. The method of claim 2 wherein the specimen from the subject is diluted in a physiologically balanced buffer.

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come *82* 15. The method of claim 2, wherein the APC in the test sample is present at from about 200 ng/ml to 1 ug/ml.--